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Section 3 510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: K132078

1. Date of Submission: 06/27/2013

2. Sponsor Identification

   Tianjin Walkman Biomaterial Co., Ltd
   No.19, Technology Road, Tianjin Tianyu Science and Technology Garden
   JinghaiEast. Tianjin, P.R. China 301609

   Establishment Registration Number: Not yet registered

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3. Submission Correspondent

   Ms. Diana Hong & Mr. Lee Fu
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4. Proposed Device Identification

Proposed Device Trade Name: Metallic Intramedullary Nail System

Classification Name: rod, fixation, intramedullary and accessories;
Classification: II;
Product Code:HSB;
Regulation Number: 21 CFR888.3020;
Review Panel: Orthopedic;

Intended Use Statement:

- Simple, compound first- and second-degree tibial shaft fractures
- Pseudarthrosis and delayed union

5. Predicate Device Identification

510(k) Number: K121312
Product Name: Intramedullary Nail System
Manufacturer: Weigao Orthopaedic Device Co., Ltd

6. Device Description

The Metallic Intramedullary Nail System, is a temporary fixation intramedullary nail designed for fracture fixation and stabilization of the tibia. The system consists of intramedullary nail, locking screw, end cap and instruments.

The intramedullary nail is available in a variety of lengths and diameters to meet assorted anatomical needs. Each of the nails is secured by a series of screws that pass through holes manufactured into the proximal and distal sections of each nail.

7. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

ASTM F 1264-03(Reapproved 2007), Standard Specification and Test Methods for Intramedullary Fixation Devices

8. Substantially Equivalent (SE) Conclusion

The following table compares the DEVICE to the predicate device with respect to intended use, technological characteristics and principles of operation, etc.

Table 3-1 Comparison of Technology Characteristics

Item		Proposed Device	Predicate Device
Product Code		HSB	Same
Regulation No.		888.3020	Same
Class		II	Same
Classification Name		Rod, Fixation, Intramedullary And Accessories	Same
Intended Use		➢ Simple, compound first- and second-degree tibial shaft fractures ➢ Pseudarthrosis and delayed union	Same
Configuration		Nail, Screw and End cap	Same
Screw Feature		Single cortical fixation achieved by proximal threaded locking screw.	Same
Sterile		The devices are supplied non-sterile, it should be sterilized prior to use by professional and the sterilization should achieve SAL 1×10^{-6}.	Same
Single Use		Yes	Same
Labeling		Conforms to 21 CFR 801	Same
Physical Specification	Nail	Proximal/Distal Diameter:φ10/φ8 mm,φ10/φ10 mm, φ10/φ9 mm Length:240 mm – 340 mm in 5 mm increments.	Proximal/Distal Diameter: φ10/φ9 mm, φ10/φ10 mm, φ11/φ9 mm, φ11/φ10 mm, φ11/φ11 mm, φ12/φ12 mm, φ13/φ13 mm Length: 240 mm – 465 mm in 5 mm increments.
	Screw	Proximally threaded screw Diameter:φ6 mm, Length: 20-75 mm	Proximally threaded screw Diameter: φ4 mm, Length: 18-80 mm Diameter: φ5 mm, Length: 26-100 mm Diameter: φ6 mm, Length: 18-100 mm
	End Cap	Diameter: φ10 mm, Length: 16mm	Diameter: φ10 mm, Length: 14 mm Diameter: φ8 mm, Length: 11.5 mm, 16.5mm, 17.5mm, 21.5mm and 26.5mm
Mechanical Specification	Nail	Tested per ASTM F1264:2003 R2007	Same
	Screw	Tested per ASTM F1264:2003 R2007	Same
Material Specification		Titanium Alloy (Ti-6Al-4V ELI)	Same
		Conforms to ASTM F136 Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI(Extra Low Interstitial) Alloy for Surgical Implant Applications (UNSR56401)	Same

The proposed device is mainly different in dimension with the predicate device, but the mechanical test demonstrated the results of both devices are very similar.

The proposed device, Metallic Intramedullary Nail System, is determined to be Substantially Equivalent (SE) to the predicate device, Intramedullary Nail System (K121312), in respect of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 19, 2014

Tianjin Walkman Biomaterial Co., Limited
% Ms. Diana Hong
General Manager
Mid-Link Consulting Co., Limited
P.O. Box 120-119
Shanghai, 200120, CHINA

Re: K132078
Trade/Device Name: Metallic Intramedullary Nail System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: February 25, 2014
Received: February 27, 2014

Dear Ms. Hong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Vincent D Devlin -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 2 Indications for Use

510(k) Number: K132078

Device Name: Metallic Intramedullary Nail System

Indications for Use:

- Simple, compound first- and second-degree tibial shaft fractures;
- Pseudarthrosis and delayed union.

☒PRESCRIPTION USE (Part 21 CFR 801 Subpart D) OR ☐OVER-THE-COUNTER USE (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices